510(k) Summary of Safety and Effectiveness

Date Prepared: December 20, 2000

Submitted by: Jomed, Inc.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact Person: Caroline Short
Phone Number: (800) 228-4728
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Device Name: Trak Back II
Common Name: Automatic Pullback Accessory
Classification Name: Diagnostic Intravascular Catheter Accessory
Predicate Device: Trak Back Disposable Pullback Device - 510(k) K9990270

Device Description:

The Trak Back II is a battery-powered device that is used in the catheterization laboratory during intravascular ultrasound assessment. The Track Back II has a nominal linear travel distance which is only limited by the catheter length, and provides a uniform, slow pull back rate of the catheter's imaging element. The speed is selectable between 0.5 mm/s and 1 mm/s. The Trak Back II has no direct patient contact. The device is constructed of materials common to the medical industry for both patient and non-patient contact devices and equipment. The Trak Back II is provided sterile for single use.

Intended Use:

The Trak Back II is designed for use with the Jomed Avanar™ family of ultrasound imaging catheters. The Trak Back II withdraws the imaging catheter from the vessel through the guide catheter.

Device Technological Characteristics and Comparison to Predicate Device:

The Trak Back II utilizes the same fundamental scientific technology and intended use as that of the predicate device, Trak Back. The design of the DC motor and electrical circuitry is the same. The difference between the two catheters lies in the drive mechanism materials. The materials of the Trak Back II have been modified to make the device compatible with Jomed's latest intravascular imaging catheters, such as the Avanar™ F/X 2.9F Catheter (K000820).

510(k) Summary (cont'd)

Performance Data:

Applicable testing was performed to evaluate the changes in the Trak Back II. The test results of the Trak Back II were found to be comparable to those of the predicate device, the Trak Back. All new materials were tested for biocompatibility according to ISO 10993.

Conclusion:

The Trak Back II utilizes the same fundamental scientific technology and intended use as that of the predicate device, Trak Back. The performance data and a declaration of conformity with design controls support a determination of substantial equivalence of the modified device, Trak Back II to the predicate device, Trak Back.

Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 8 2001

Ms.Christina Kichula
Jomed, Inc.
c/o Eminent Research Systems, Inc.
1700 Rockville Pike
Suite 400
Rockville, MD 20852

Re: K003938
Trade Name: Trak Back II
Regulatory Class: II (two)
Product Code: DQO
Dated: December 20, 2000
Received: December 20, 2000

Dear Ms. Kichula:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003938

Device Name: Trak Back II

Indications for Use:

The Trak Back II is designed for use with the Jomed Avanar™ family of ultrasound imaging catheters. The Trak Back II withdraws the imaging catheter from the vessel through the guide catheter.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003938

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)